

Authorization of Use for Certain Lots of Expired Tamiflu and Relenza

Eighteen lots of Tamiflu Capsules and three lots of Relenza Inhalation Powder have been authorized by FDA for use beyond their expiration dates. FDA has authorized the use of these lots beyond their expiration dates under Emergency Use Authorizations ([Tamiflu EUA](#) and [Relenza EUA](#)) that specify certain conditions of use. FDA's decision to authorize the use of these lots beyond their expiration dates is supported by FDA's approval of applications submitted by the manufacturers of Tamiflu and Relenza that extended the expiration dates of certain Tamiflu and Relenza products.

These lots are only authorized for use beyond their expiration dates under the EUAs during the period of time that the Secretary of the Department of Health and Human Services' (HHS's) April 26, 2009 declaration of emergency justifying the EUAs remains in effect. The declaration will expire in one year, on April 26, 2010, unless it is terminated earlier, but it could be extended by the Secretary of HHS if certain criteria are met.

Entities holding any of the lots identified below may wish to consider retaining them following termination of the declaration of emergency in the event that their use may be authorized under an EUA in a future declared emergency. If the entity decides to retain such lots of Tamiflu and/or Relenza, they should be maintained and monitored under the products' labeled storage conditions.

1. The updated webpages with the authorized lots have been posted. Links below:

<http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.htm>

<http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm100228.htm#Stockpile>

2. The Tamiflu Letter of Authorization and both Fact Sheets have been posted. Link below:

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm107838.htm>

3. The Relenza Letter of Authorization and both Fact Sheets have been posted. Links below:

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm183783.htm>

4. The EUA Q&As have been posted. Link below:

<http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm153228.htm>